trated with an example that highlights pitfalls involved with more simplistic approaches.

PRM63

CLOSING THE GAP BETWEEN THE FORMULATION AND IMPLEMENTATION OF CLINICAL PRACTICE GUIDELINES BASED ON EVIDENCE

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**OBJECTIVES:** To describe the theoretical approach suggested to close the gap between recommendations and implementation of clinical practice guidelines (CPG's) in Colombia, called harmonization of CPG's with Public Policy. **METHODS:** Perspective paper. A theoretical approach is suggested to harmonize CPG's recommendations with public policy. **RESULTS:** Public policies often don't get the desired results, because there is a gap between the decision and the reality. There is a conceptual and temporal separation between policy formulation and implementation of decisions, CPG's are tools to improve quality in the delivery of health services. However a process od harmonization between recommendations and implementation with public policy is requested. For this a process of three phases should be developed: 1) To do a review of existing regulations on health and on the specific issue of the CPG to harmonize the current policy with recommendations and identify barriers to the implementation process; 2) To adjust recommendations of CPG's to eliminate the barriers encountered with the standards; 3. To state a negotiation process with all actors involved in the implementation of the CPG's at different levels of care, to generate commitment with them, proposals for changes in policy and / or administrative, and if it is necessary, to remove barriers **CONCLUSIONS:** Harmonization of CPG's with public policy is a fundamental tool to improve their implementation. Three phases are proposed. Negotiation could be the most important one.

PRM64

SOCIETAL PERSPECTIVE IN ECONOMIC EVALUATION: CONFUSIONS AND HIRA'S RECOMMENDATION

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**BACKGROUND:** Current HIRA's guideline recommends that economic evaluation (EE) analysis should take societal perspective, yet the inconsistency in current guideline has been noted by the industry side. The purpose of this study is to review current theoretical trends and discuss the needs of updating HIRA's current recommendations. **METHODS:** To identify the needs of EE guideline revision, HIRA has reviewed currently updated foreign EE guidelines, and discussed recent theoretical trends. In addition, survey results from pharmaceutical companies as well as decision makers regarding current recommendation were considered. Experts meetings and working group meetings with industry people were held to share each party's perspectives. **RESULTS:** Pharmaceutical industry suggested that current recommendation of taking societal perspective while submitting indirect cost (especially productivity cost) separately is confusing. Canada (CADTH) has recently updated its perspective as "publicly funded health care system", and UK (NICE) has recommended to take payer(NHS and PSS)'s perspective. Inconsistencies in societal perspective have also discussed in previous studies and ISPOR consensus paper. **CONCLUSIONS:** Given that EE guideline should provide clear minimum standards for submission parties, a need to clarify current "societal" perspective has been agreed by relevant parties. "Limited" societal perspective has been proposed to reduce unnecessary confusions while reflecting current practice patterns.

PRM65

PREVALENCE-BASED VERSUS INCIDENCE-BASED ECONOMIC EVALUATIONS FOR THE ASSESSMENT OF NEW HEALTH CARE INTERVENTIONS

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**OBJECTIVES:** To compare the usefulness to decision makers of prevalence-based versus incidence-based economic evaluations of new health care interventions **METHODS:** Comparison of evaluation methods by: population included, time horizon, outcomes measured, adherence to economic principles, and usefulness to decision makers. **RESULTS:** An incidence-based economic evaluation follows a disease cohort for the duration of the disease and estimates discounted costs and health gains with alternative interventions. The cost-effectiveness ratio is based on individual utility maximization and provides information to decision makers about the efficiency of a new healthcare intervention compared to societal willingness to pay for health gains. It does not estimate annual budget impacts. It generally does not capture indirect effects on the population. A prevalence-based economic evaluation provides estimates of costs and health benefits for the total population for one year or cumulated over a longer time horizon. The estimated ratio of cumulative costs and health benefits is not based on economic principles. Appropriate threshold values for these ratios are those based on a percentage of Gross Domestic Product as recommended by the World Health Organization. The prevalence-based cost-effectiveness ratio provides information to decision makers on the affordability of the intervention and the value for money over the selected time horizon. A prevalence-based analysis can take into account indirect effects of health care interventions and is, therefore, frequently used for economic evaluations of vaccine programs. **CONCLUSIONS:** Prevalence-based economic evaluations might be of greater use to health care decision makers than incidence-based evaluations because, in addition to estimates of value for money, they provide estimates of affordability and allow comparison of all types of health care interventions. Threshold values based on economic principles, however, are not applicable for ratios generated using the prevalence-based approach.

## DISEASE-SPECIFIC STUDIES

### DIABETES/ENDOCRINE DISORDERS – Clinical Outcomes Studies

PDB1

COMPARING HYPOGLYCEMIA RATES FOR TYPE 2 DIABETES PATIENTS TREATED WITH SAXAGLIPTIN VERSUS SULFONYLUREA: USING CLAIMS DATA TO REPLICATE A CLINICAL TRIAL

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**OBJECTIVES:** A lower rate of hypoglycemia occurred in a Phase 3 trial in T2DM patients receiving saxagliptin compared to glipizide (sulfonylurea (SU)) added to metformin. The clinical trial included patient-reported and physician-reported hypoglycemia events. The objective of this study was to compare the rates of hypoglycemia events that required medical attention in actual clinical practice. **METHODS:** *MarketScan* health care claims data was used to identify patients who initiated saxagliptin or SU. During the 6 months prior to initiation, patients were required to have a prescription (Rx) for metformin and no saxagliptin, SU, or other diabetes Rx. Patients were followed for 4 months to assess the rates of hypoglycemia. During follow-up, patients were required to have at least one more metformin Rx and one additional saxagliptin/SU Rx and no other diabetes Rx. A hypoglycemia event was defined as a diagnosis of hypoglycemia on an outpatient or emergency room claim or principal diagnosis on a hospital claim or an outpatient glucagon injection. SU patients were matched to saxagliptin patients (5 to 1) using propensity scores. The rate ratio was further adjusted for covariates that were not balanced between the matched cohorts using a Poisson regression model. **RESULTS:** There were 1,567 saxagliptin, 21,025 SU, and 7,835 propensity-matched SU patients. The rate of hypoglycemia in the saxagliptin cohort was 1.74 per 100 PY versus 6.68 in the SU cohort (rate ratio 0.31, 95% CI: 0.14 – 0.60) and 4.45 per 100 PY in the matched SU sub-group (rate ratio 0.39, 95% CI: 0.17 – 0.77). After multivariate adjustment, the rate ratio was 0.37 (95% CI: 0.19 – 0.74). **CONCLUSIONS:** In real world practice, as was demonstrated in a randomized controlled trial, saxagliptin patients had a lower risk of hypoglycemia than SU when added to metformin.

PDB2

VITAMIN B AND/OR ITS DERIVATIVES FOR DIABETIC KIDNEY DISEASE: A SYSTEMATIC REVIEW AND META-ANALYSIS

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**OBJECTIVES:** To assess the benefits and harms of vitamin B and/or its derivatives in patients with diabetic kidney disease (DKD). **METHODS:** We searched the Cochrane Renal Group's Specialized Register CENTRAL; MEDLINE OVID SP; Hand searching of renal journals and conference proceedings; EMBASE OVID SP; the International Clinical Trials Register (ICTRP) Search Portal & ClinicalTrials.gov. Randomized controlled trials (RCTs) comparing vitamin B and/or its derivatives with placebo, no or active treatment, in patients with DKD were included. **RESULTS:** Out of 56 identified studies, four studies were found to be suitable for inclusion. A total of 745 participants were randomized to either vitamin B derivatives (benfotiamine (300 mg TID), thiamine (300 mg OD), vitamin B12 (500 mg OD), folic acid (2.5 mg OD), vitamin B6 (25 mg OD)) or placebo or active control. Treatment duration ranged from 3 months to 36 months. We found that none of those derivatives improved kidney function: improved creatinine clearance (Mean difference (MD) 2.00, 95% CI -21.78 to 25.78, P = 0.87), decreased serum creatinine level (MD 1.00, 95% CI -7.88 to 9.88, P = 0.83), reduce level of urinary albumin excretion level (MD: -16.75, 95% CI -103.44 to 69.94, P = 0.70), improved the glomerular filtration rate (MD: -7.00, 95% CI -22.33 to 8.33, P = 0.37) significantly compared to placebo or active control. In addition, we found that risk of myocardial infarction, stroke, revascularization, and all-cause mortality, in the B-vitamin combination therapy group was increased (Risk Ratio 1.85, 95% CI 0.99 to 3.45, P= 0.05). We also found no significant difference between vitamin B combination therapy and control group for serious adverse events, and one or more adverse events. **CONCLUSIONS:** We did not find any improvement in kidney function, following use of vitamin B preparation. These findings require confirmation from high quality randomized trials.

PDB3

RISK OF COMPLICATIONS IN TYPE II DIABETIC PATIENTS WITH RENAL IMPAIRMENT: AN ANALYSIS OF THE RAMQ DATABASE

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**OBJECTIVES:** Chronic kidney disease is often associated with type II diabetes mellitus (T2DM). Patients with T2DM and chronic renal failure are at higher risk of developing hypoglycemia or metabolic acidosis. The purpose of this study was to identify treatment patterns in T2DM patients with chronic renal failure and to estimate the risk of developing complications. **METHODS:** This study examined data on patients covered by the Quebec provincial drug reimbursement program (RAMQ) who had a diagnosis of diabetes, had used a hypoglycemic agent, and had a diagnosis of chronic renal disease in the period from January 2005 to December 2010. A 1:1 control group of patients with diabetes and without renal disease, matched for age and gender, was also created. Patients' characteristics and drug utilization patterns were analyzed and the risks of experiencing hypoglycemia or metabolic acidosis were estimated. **RESULTS:** A total of 4889 patients who had a diagnosis of diabetes with chronic renal failure were included in this cohort. Aver-